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## Medicines Safety Assurance Tool August 2019

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)



Midlands and Lancashire  
Commissioning Support Unit

### Reminder: citalopram and escitalopram - QT interval prolongation

MHRA | December 2011

Citalopram and escitalopram may have an additive effect to other drugs that prolong the QT interval. Coadministration of citalopram and escitalopram with medicines that prolong the QT interval is therefore contraindicated. Experience shared by NHS St Helens CCG highlighted the contraindication between citalopram and formoterol which itself may induce prolongation of the QTc interval.

<https://www.gov.uk/drug-safety-update/citalopram-and-escitalopram-qt-interval-prolongation>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

### Emerade 500 Microgram and 300 Microgram Adrenaline Auto-Injector Devices manufactured by Bausch & Lomb UK

Central Alerting System | 01 August 2019

Emerade 500 microgram and 300 microgram devices manufactured by Bausch & Lomb UK will be experiencing a short-term disruption in supply. Emerade 500 microgram is out of stock until the 28 August 2019. Emerade 300 microgram has limited supplies remaining but will be out of stock from early-mid August with further supplies expected by 30 September 2019. The alert also provides a management plan for organisations to follow in managing stock.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102885>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

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### Elmiron (pentosan polysulfate sodium): risk of pigmentary maculopathy

Consilient Health Ltd | 19 August 2019

Letter advises that rare cases of pigmentary maculopathy (PM) have been reported, especially after long term use. During treatment patients should have regular eye examination for early detection of PM and seek medical advice in case of visual changes.

[https://assets.publishing.service.gov.uk/media/5d56c8fded915d08d02e5489/Elmiron\\_DHPC.pdf](https://assets.publishing.service.gov.uk/media/5d56c8fded915d08d02e5489/Elmiron_DHPC.pdf)

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

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### Naltrexone/bupropion (Mysimba): risk of adverse reactions that could affect ability to drive

Medicines and Healthcare products Regulatory Agency | 19 August 2019

People on Mysimba may commonly experience dizziness/somnolence, and may rarely experience loss of consciousness/seizure, especially, at beginning of treatment/during dose titration. If these ADRs occur, they should be advised not to drive/operate machinery until they have resolved.

<https://www.gov.uk/drug-safety-update/naltrexone-bupropion-mysimba-risk-of-adverse-reactions-that-could-affect-ability-to-drive>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

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### Can miconazole oral gel be used by patients taking a statin?

Specialist Pharmacy Service | 27 August 2019

This updated Medicines Q&A explores the evidence for the interaction between miconazole oral gel and statins.

<https://www.sps.nhs.uk/articles/can-miconazole-oral-gel-be-used-by-patients-taking-a-statin-2/>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

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### Hormone replacement therapy (HRT) and increased risk of breast cancer

Medicines and Healthcare products Regulatory Agency | 30 August 2019

Further information on the known increased risk of breast cancer with HRT and its persistence after stopping. New data has confirmed the risk of breast cancer is increased during use of all types of HRT, except vaginal estrogens, and has also shown an excess risk of breast cancer persists for longer after stopping HRT than previously thought. Prescribers of HRT are advised to discuss the updated total risk with women using HRT at their next routine appointment

<https://www.gov.uk/drug-safety-update/hormone-replacement-therapy-hrt-further-information-on-the-known-increased-risk-of-breast-cancer-with-hrt-and-its-persistence-after-stopping>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

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## Summary of Product Characteristics Update

Electronic Medicines Compendium | August 2019

### Adenuric (febuxostat) 80 and 120 mg film-coated tablets

Sudden cardiac death has been added to SPC as a rare adverse drug reaction and warning for patients with pre-existing CV disease has been reworded.

<https://www.medicines.org.uk/emc/product/487/smpc>

### Adoport (tacrolimus) products

SPC now notes that eye disorders, sometimes progressing to loss of vision, have been reported with tacrolimus. Patients should be advised to report changes in vision and in such cases, prompt evaluation is recommended with referral to an ophthalmologist as appropriate.

<https://www.medicines.org.uk/emc/product/585/smpc>

### Atorvastatin Film Coated Tablets (all strengths)

SPC updated to include muscle rapture as a rare side effect on recommendation of the Pharmacovigilance Risk Assessment Committee.

<https://www.medicines.org.uk/emc/product/5275/smpc>

### Cipralext (escitalopram) products

SPC now advises that there have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs.

<https://www.medicines.org.uk/emc/product/4306/smpc>

### Combined Hormonal Contraceptives (CHCs)

Bayer has published a checklist for prescribers, a Q&A on important information for women and a summary of important information about risk of blood clots with combined hormonal contraceptives, for all Bayer CHC products.

<https://www.medicines.org.uk/emc/product/1124/rmms>

### Coversyl (indapamide/ perindopril arginine) tablets

Raynaud's phenomenon has been added as an adverse event to the SPC (frequency unknown).

<https://www.medicines.org.uk/emc/product/6223/smpc>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

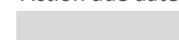
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Action due date

Date completed



**Crestor (rosuvastatin) film-coated tablets**

Lupus-like syndrome and muscle rupture have been added as adverse events to the SPC (frequency rare for both).

<https://www.medicines.org.uk/emc/product/7554/smpc>

**Cymbalta (duloxetine) 30 and 60mg hard gastro-resistant capsules**

SPC revised to highlight that observational data have provided evidence of an increased risk (less than 2-fold) of postpartum haemorrhage following duloxetine exposure within the month prior to birth.

<https://www.medicines.org.uk/emc/product/7450/smpc>

**Cynril (fentanyl) Lozenges- all strengths**

Delirium has been added to SPCs as an adverse effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/10166/smpc>

**Desitrend (levetiracetam) coated granules in sachet- all strengths**

SPC revised to advise that after oral administration, the bitter taste of levetiracetam may be experienced, and gait disturbance has been added as a rare adverse event.

<https://www.medicines.org.uk/emc/product/2883/smpc>

**Diclofenac Sodium Gastro-Resistant and Prolonged-release Tablets (all strengths)**

SPC revised to add anastomotic leakage and 'Kounis syndrome' (allergic acute coronary syndrome) as adverse reactions of unknown frequency.

<https://www.medicines.org.uk/emc/product/2660/smpc>

**Diprosalic (betamethasone dipropionate) products**

SPCs have been updated with new MHRA mandated statement regarding the fire hazard risk of fabric that has been in contact with Diprosalic.

<https://www.medicines.org.uk/emc/product/1450/smpc>

**Durogesic (fentanyl) DTrans Transdermal Patch (all strengths)**

Androgen deficiency has added to SPC as an adverse effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/157/smpc>

**Efexor XL (venlafaxine) products**

SPC has been updated with the addition of a warning regarding sexual dysfunction after drug withdrawal.

<https://www.medicines.org.uk/emc/product/5474/smpc>

**EpiPen Adrenaline (Epinephrine) 0.3 mg Auto-Injector**

Shelf life has been extended from 20 months to 24 months.

<https://www.medicines.org.uk/emc/product/4289/smpc>

**Forxiga (dapagliflozin) 5mg film-coated tablets**

The SPC has been updated to include data from DECLARE study which compared dapagliflozin 10 mg with placebo in 17,160 patients with type 2 diabetes mellitus with or without established cardiovascular disease to evaluate the effect on cardiovascular and renal events.

<https://www.medicines.org.uk/emc/product/2865/smpc>

**Ganfort 0.3 mg/ml + 5 mg/ml (timolol maleate, bimatoprost) eye drops (all products)**

SPCs revised to include hallucination as an undesirable effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/1239/smpc>

**Glycopyrronium bromide 1 mg/5 ml oral solution**

Colonis Pharma have published a checklist for healthcare professionals for assessment of anticholinergic effects & a reminder card for caregivers on how to manage common side effects and important information on administration of glycopyrronium bromide 1 mg/5 ml oral solution.

<https://www.medicines.org.uk/emc/product/7344/rmms>

**Largactil (chlorpromazine) preparations**

SPC now advises that administration of chlorpromazine with CYP1A2 inhibitors, strong or moderate inhibitors may lead to an increase of chlorpromazine plasma concentrations. Therefore, patients may experience a chlorpromazine dose-dependent adverse drug reaction.

<https://www.medicines.org.uk/emc/product/957/smpc>

#### **Lustral (sertraline) 50 and 100mg film coated tablets**

SPC updated to warn that SSRIs may cause symptoms of sexual dysfunction, with reports of long-lasting sexual dysfunction where the symptoms have continued despite treatment discontinuation. Maculopathy has also been added as adverse effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/2835/smpc>

#### **Menitorix (hib meningococcal group c combined vaccine) Powder and solvent for solution for injection**

SPC warns individuals with familial complement deficiencies & those receiving treatments that inhibit terminal complement activation are at increased risk for invasive disease caused by Neisseria meningitidis group C, even if they develop antibodies following vaccination.

<https://www.medicines.org.uk/emc/product/167/smpc>

#### **Montelukast preparations**

SPC now details that patients and physicians should be alert for potential neuropsychiatric adverse events. Prescribers should carefully evaluate the risks and benefits of continuing treatment with montelukast if such events occur.

<https://www.medicines.org.uk/emc/product/3499/smpc>

#### **Pneumovax (pneumococcal vaccine) 23 solution for injection in pre-filled syringe**

The SPC has been updated to include data collected from a large observational study which did not indicate an increased risk for developing herpes zoster after concomitant administration with Zostavax (varicella-zoster virus live) vaccine.

<https://www.medicines.org.uk/emc/product/9692/smpc>

#### **Prostap 3 DCS 11.25 mg (leuprorelin) Prolonged Release Injection in Pre-filled syringe**

SPC now advises that the 3 monthly formulation should not be used to preserve ovarian function in premenopausal women undergoing chemotherapy treatment as there are no data demonstrating effectiveness of the 3-monthly product for this use.

<https://www.medicines.org.uk/emc/product/4651/smpc>

#### **Saxenda (liraglutide) 6 mg/mL solution for injection in pre-filled pen**

Following MHRA drug safety update, SPC has been revised to warn that in patients with diabetes mellitus, liraglutide must not be used as a substitute for insulin (IN) and DKA has been reported in IN dependent patients after rapid discontinuation or dose reduction of IN.

<https://www.medicines.org.uk/emc/product/2313/smpc>

**Vimpat (lacosamide) preparations**

SPC now specifies that loading doses should be administered under medical supervision with consideration of the potential for increased incidence of serious cardiac arrhythmia and CNS adverse drug reactions.

<https://www.medicines.org.uk/emc/product/2285/smpc>

**Voltarol (diclofenac potassium) - all products**

SPCs revised to warn patients should remain alert for signs & symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings; and to see a physician immediately in case of such an event.

<https://www.medicines.org.uk/emc/product/4333/smpc>

**Xatral (alfuzosin hydrochloride) 2.5mg Film-coated Tablets and Xatral XL 10mg prolonged release tablets**

SPC updated to state concomitant use of alfuzosin and potent CYP3A4 inhibitors (e.g. itraconazole, protease inhibitors & clarithromycin) should be avoided and temporary interruption of alfuzosin treatment is recommended if treatment with such medicinal products is initiated.

<https://www.medicines.org.uk/emc/product/1474/smpc>

**Xigduo (dapagliflozin/metformin) film coated tablets- all strengths**

Restriction on use in patients aged 75 years and above has been removed, as has recommendation against use in patients receiving loop diuretics and precaution for patients with known cardiovascular disease.

<https://www.medicines.org.uk/emc/product/5293/smpc>

**Yentreve (duloxetine) 20 and 40mg hard gastro-resistant capsules**

SPC revised to highlight that observational data have provided evidence of an increased risk (less than 2-fold) of postpartum haemorrhage following duloxetine exposure within the month prior to birth.

<https://www.medicines.org.uk/emc/product/5561/smpc>

**Zestril (lisinopril) tablets- all strengths**

SPCs updated to contraindicate concomitant use with sacubitril/valsartan, as well as change to hyperkalaemia warning in line with PRAC recommendation, and further information on potassium supplementation and new interaction with ciclosporin and heparin added.

<https://www.medicines.org.uk/emc/product/3269/smpc>